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ENHANCED SURFACE AREA SPINAL FUSION DEVICES AND ALIGNMENT APPARATUS THEREFOR

Reference to Related Application

This application is a continuation-in-part of U.S. patent application Serial No. 09/483,805, filed January 15, 2000, the entire contents of which are incorporated herein by reference.

Field of the Invention

This invention relates generally to corrective spinal surgery and, in particular, to vertebral fusion devices providing a greater surface area to enhance fusion.

Background of the Invention

In conjunction with spinal surgery, interbody fusion cages are regularly placed between the end-plates of the vertebra to aid in fusion. This is justified on the basis that the end plates of the vertebra are stronger than the cancellous bone within the body of the vertebra, enabling the strength of the end plates to be relied upon for distraction. Such distraction restores the disc space height, thereby hopefully alleviating pressure on the spinal nerves and, hopefully, reducing pain or discomfort, if present.

Fusion is more successful if done in cancellous bone, however. Thus, when performing interbody fusion, the surgeon must balance preserving the end plates for support while removing at least a portion thereof to aid in fusion. To achieve this balance, the surgeon typically scraps or decorticates a portion of the opposing end plates

to expose the underlying cancellous bone.

Figures 1A and 1B illustrate, from an oblique perspective, existing prior-art devices such as strut graft 100 and cages 101 used for distraction and/or fusion. It is important to note that, although Figure 1A implies the use of strut graft 100 and cages 101 used in combination, they are used separately according to the current practice. That is, when a strut graft is used, cages are not, and when cages are used, they occupy the entire intervertebral space, thereby precluding the use of a strut graft. Nevertheless, both are shown in the figure as the alternatives currently in use. The strut graft 100 is typically an elongated body dimensioned to extend from the inferior end plate 108 of vertebra 102 to the superior end plate 110 of vertebra 106, also extending through an intermediate vertebra 104 through a slot 112. Those of skill appreciate that longer members, penetrating through a plurality of slotted vertebra are also in use. Figure 1B illustrates the arrangement from a transverse section taken through vertebra 104.

To install the graft 100, the channel 112 is formed into one or more intermediate vertebra using chisels or power burrs. The walls formed through the vertebra are accordingly irregular, reducing the likelihood of contact points 120 between the device 100 and the walls of the slot. As best seen in Figure 1B, even if a perfectly rectangular slot were to be formed through intermediate vertebra 104, the points of contact would be limited to points 120. The decreased contact area increases the likelihood of device migration and failure of fusion. In addition, only a small portion 109 of the inferior end plate 108 of vertebra 102, and a correspondingly small portion (covered by the end of

device) of superior end plate of vertebra 106 is scraped away and allowed to fuse with the ends of the graft 100, the result being a structure which is less than optimal. The area for fusion adjacent to the endplates is even smaller with interbody fusion cages 103.

Summary of the Invention

The subject of the present invention resides in enhanced surface area spinal fixation devices. Broadly, in contrast to existing intervertebral cages and strut grafts, which minimally penetrate the cortical endplates of the vertebra to be fused, devices according to the invention have upper and lower sections which are implanted directly within the bodies of the vertebra being fused, thereby surrounding the implanted sections with cancellous bone which is more conducive to ingrowth and permanent fusion.

In the preferred embodiment, a spinal fixation device according to the invention comprises a frame-like structure composed of biocompatible material such as carbon fiber, having a substantially hollow interior and open side walls, ends, or apertures to receive bone-graft material. The device is preferably used in conjunction with adjoining intervertebral cages, which may be rigidly joined to one another and/or to the inventive device. The cages rely on retained endplates for distraction. Wedge-shaped distraction plugs, similar to intervertebral cages, may alternatively be employed. Since fusion occurs through the device to enhance surface area, such plugs may be solid.

The spinal fixation device also preferably further includes one or more physical features to engage with surrounding bone or minimize back-out, such as teeth, ridges, grooves, or outriggers. One or more shape-memory elements may also be used, each of

which is preferably compressed for insertion then expanded when the device is in place.

The inventive fixation device need not be employed between adjacent vertebra, but may be used between vertebra separated by one or more intermediate vertebra, in which case the device extends through the intermediate vertebra, preferably in intimate contact therewith. Multiple devices may also be implanted side by side between the same set of adjacent vertebra. In addition to these various alternative embodiments of the invention, a preferred method of installation is also disclosed. In one of the methods, one or more fasteners, installed with an alignment guide, provide additional fixation.

Brief Description of the Drawings

FIGURE 1A is a drawing providing a perspective view of prior-art devices used for intervertebral fusion, including a strut graft and cages placed between vertebral end plates;

FIGURE 1B is a cross-section of a vertebra of Figure 1A, showing the way in which the strut graft contacts a slot formed therethrough;

FIGURE 2A is a drawing providing a perspective view of an enhanced surface area spinal fusion device according to the invention in conjunction with intervertebral cages and optional fixation devices;

FIGURE 2B is a cross-section of a vertebra of Figure 2A, showing the enhanced surface area viewed from a top-down perspective;

FIGURE 3A is a schematic anterior-posterior view of an enhanced surface area fusion device according to the invention cooperating with three vertebra;

FIGURE 3B is a schematic anterior-posterior view of a plurality of devices according to the invention installed between adjacent vertebra;

FIGURE 3C is an oblique representation of a device according to the invention wherein an enhanced surface area device is integrally formed with side members obviating the need for separate intervertebral cages;

FIGURE 4A is an oblique drawing which shows how elongated ridges may be used to minimize back-out of a device according to the invention;

FIGURE 4B is a drawing which shows how barbs, including shape-memory barbs may be used in conjunction with a device to minimize back-out;

FIGURE 4C is a drawing which shows how screws or other fasteners in different orientations may be used to fix an enhanced surface area device according to the invention in place;

FIGURE 4D is a drawing which shows the use of metal or plastic plugs, preferably made with a shape-memory material, which expands after implantation to hold an enhanced surface area device in place;

FIGURES 5A to 5K are drawings which show a preferred method resecting vertebra through the installation of an enhanced surface area spinal fusion device according to the invention;

FIGURE 6A is an end view of a vertebra, showing a fusion device and alignment guide according to the invention;

FIGURE 6B is a drawing which illustrates a drill having been received by the

alignment guide;

FIGURE 6C is a drawing which shows the way in which the guide can be used to receive a screwdriver for inserting a threaded fastener into the predrilled hole; and

FIGURE 6D is a frontal view drawing which illustrates screws having been installed according to the method and apparatus of this invention to provide additional fixation for the fusion device.

Detailed Description of the Invention

Turning now to Figures 2A, there is shown, from an oblique perspective, an enhanced surface area spinal fusion device according to the invention, generally at 200. The device is preferably frame-like having a lower section L, a middle M, and an upper section U. The device 200 further preferably comprises multiple passageways or apertures 202 into which bone-graft material may be placed to aid in fusion overall. Although the apertures 202 depicted in Figure 2A are rectangular in shape, other geometries may be used, as appropriate, including circular and oval openings.

The device 200 fits into slots 204 and 206 made in upper and lower vertebra 208 and 210, respectively, allowing the lower section to fuse within the body of the lower vertebra 210, and the upper section to fuse within the body of the upper vertebra 208. Thus, in contrast to existing devices, the device 200 and the alternative embodiments disclosed herein feature considerably more intimate contact with cancellous bone due to the fact that the device is inserted directly into the cavities 204 and 206. Rather than a relatively minor amount of scraping of the end plates of the vertebra to be distracted, the

entire end portions of the device 200 which penetrate the upper and lower vertebra make contact with cancellous bone, thereby enhancing fusion considerably. Figure 2B is a cross-section of a vertebra of Figure 2A as viewed from a top-down perspective, showing how the device fits tightly along the entire walls of the channels created in the vertebra.

The device 200 is preferably constructed in the cage-like manner, allowing bone ingrowth material to be inserted into the openings at 202, thereby further promoting ingrowth once installed. The teeth 216, ridges or other devices disclosed elsewhere herein further assist in engaging with bone to maintain stability. Other arrangements to prevent back-out discussed with reference to Figures 4A through 4D may also be used. Although the drawing of Figure 2 shows the device 200 interposed between adjacent vertebra, it may fuse vertebra which are not adjacent, in which case the intermediate vertebra would be slotted from their superior to inferior surfaces, much like slot 112 of vertebra 104 in Figures 1A and 1B. As shown in Figure 3B, the invention is not limited to the use of a single device per vertebra to be fused, but two or more devices may be used, each engaging with separate slots.

In contrast to existing strut grafts and cages, which are used separately and not in combination, the device 200 may be used with cages 220, preferably filled with bone-graft material. An optional transverse bar 222 may also be used, not only to fasten the cages 220 together, but a point of fastening 224 may be provided on the device 200 as well, forming an integral unit. Conventional intervertebral cages may be used or, alternatively, cages may be used of the type described in my co-pending U.S. patent

application Serial No. 09/454,908, the entire contents of which are incorporated herein by reference. As a further alternative, an enhanced surface area device may be integrally formed with side members acting as cages, resulting in the cruciate configuration of Figure 3C. Additional fixation devices such as one or more plates 224, may be used to provide additional stability.

Devices according to the invention may be constructed of various materials, though, in the preferred embodiment, carbon fiber would be used. Whereas current struts are made of metal or bone, carbon fiber devices would allow x-ray determination of fusion to be more easily assessed. Devices according to the invention may, however, be composed of metal or bone and, if composed of bone, the aperture such as 202 would not need to be provided, since a solid piece of bone graft may be used. The device may also be covered with a bone ingrowth material such as titanium mesh or plasma spray. Plastic or ceramics may also be used, as appropriate.

As discussed above, various structures and mechanisms may be used to hold a device according to the invention in place. In addition to the preferred use of teeth 216 in Figure 2A, one or more sides of the device may have ribs or ridges as shown in Figure 4A to assist in preventing back-out. As an alternative, barbed projections or outriggers may be used as shown in Figure 4B, and may incorporate spring-biased or shape-memory materials to ease insertion while allowing for expansion following introduction of the device. As shown in Figure 4C, one or more screws may be used to fix the device medially-laterally or directly into the superior/posterior vertebra being fused.

Figure 4D illustrates the use of distraction plugs 440 according to the invention, wherein pieces of metal, plastic, bone or other suitable materials such as carbon fiber are attached to the sides of the device 420, either using fasteners such as screws 444, a transverse bar 446, or both. In a preferred embodiment, the plugs would be made of carbon fiber, whereas the transverse connector would preferably be made of titanium. As an alternative to a rigid material, the plugs may incorporate a shape-memory material, which would allow for easy insertion of device, but would prevent the device from backing out once installed. To assist in positioning, recesses 448 may be provided on either sides of the device 420. The plugs may be rectangular or wedge-shaped to account for lordosis, as described in my co-pending U.S. patent application referenced above.

Figures 5A through 5K illustrate preferred steps associated with the installation of a device according to the invention. Although the system is preferably designed for an anterior approach, the invention is not limited in this manner, and may be placed posteriorily, with rods, screws, etc. applied through separate incisions, as appropriate.

Figure 5A is a drawing which shows how a midline 502 would first be determined using fluoroscopy. As shown in Figure 5B, the anterior annulus and nucleus pulpous or, at least a portion of the nucleus would be removed for distraction and insertion of the inventive device. Figure 5C is a simplified drawing which shows an insertion tool 510 used to install distracters 512. Such a device preferably includes screws 514 to hold the distracter to the insertion tool until it is removed. Figure 5D shows the distracters in place medially and laterally between adjacent vertebra.

In Figure 5E, a guide 520 has been installed over adjacent vertebra which is used including a slot 522 to receive a device such as box chisel 524. Other instruments such as a bone saw may be used, but in any case, stops are used to ensure that the channel has a depth preferably in the range of 15-30 mm. Figure 5F illustrates a rectangular shaped slot formed between adjacent vertebra once the box chisel 524 of Figure 5E has been removed. To perform the posterior cuts and remove the pieces, a tool such as that shown in Figure 5G having cutting edges 540 and depth stops 541 is preferably used. When the handles 542 of the tool are squeezed, the cutting edges are away from one another, allowing them to resect bone above and below.

Figure 5H is a side-view drawing showing the tool of Figure 5G in place, with the distraction plugs removed for clarity of illustration. Figure 5I is a side-view drawing illustrating how the pieces of cut bone would preferably be removed with a saw or box chisel. In particular, a cutting tool such as an osteotome 550 would be used to progressively penetrate the anterior wall and, by tapping the cutting blade posteriorily, slices may be formed and removed until the final slots are formed. Care must be taken so as not to disturb the final cuts, however. The device is then inserted, as shown in Figure 5J, and additional fixation devices are used, as described elsewhere hereinabove to prevent back-out. Figure 5K is a drawing providing a perspective view of a multilevel spinal fusion device according to the invention with distraction plugs or intervertebral cages (shown as 560), transverse connectors 564, and element 570 to prevent back-out.

In addition to the enhanced surface area made possible by the invention for

fixation, another advantage is that the bone material removed to form the slots as just described may be used to fill the device, obviating the need to harvest additional bone from the patient. Harvesting bone graft is painful, typically delays a patient's recovery, and could cause complications such as fracture, infection or nerve injury.

To provide additional fixation of fusion devices according to the invention, fasteners may be inserted through the vertebra and fusion device. For example, a fastener such as a screw may be installed through vertebra 208, 210 and through apertures such as 202, thereby providing an additional level of stability. Although holes for such fasteners may be drilled free hand, this invention also anticipates the use of an alignment guide to ensure that the fasteners properly extend through the bone and fusion device.

Preferred apparatus to carry out this inventive method is depicted in Figures 6A-6D. Figure 6A shows the attachment of an alignment guide 604 directly onto an enhanced surface area spinal fusion device 602 according to the invention through the use of a fastener such as screw 606. At the other end of the alignment guide 604, is a rigidly affixed drill/screw guide 610, the assembly being configured such that when the guide is properly attached to the fusion device, the drill/screw 610 is properly oriented and aimed for the receipt of a fastener through the vertebra 600 and fusion device 602.

The use of a drill 620 is shown in Figure 6B, along with the use of a sleeve 622 to protect the inner bore of the alignment guide, if necessary. Using such an arrangement, a hole 626 is accurately drilled through a corresponding hole in the fusion device 602. Given the accurate alignment made possible by this configuration, the hole through the

fusion device 602 need not be a large aperture, but may instead be a small hole just larger than the drill. Of course, if the fusion device 602 contains areas of softer, drillable material, a hole need not be provided in the fusion device at all, insofar as the drill may penetrate therethrough.

Having drilled through the vertebra 600, a screw 630 shown in Figure 6C is received by the hole drilled by drill 620, with the sleeve 610 being used now to receive a screwdriver 640 to anchor the fastener 630 in place.

Figure 6D is a frontal view of the completed assembly, showing screws 630' and 630'' respectively extending through upper vertebra 600' and 600''. The fusion device is shown at 602, along with distraction plug 650.

I claim: